

William J. O'Shaughnessy
MCCARTER & ENGLISH LLP
Four Gateway Center
100 Mulberry Street
Newark, NJ 07102
(973) 639-2094
woshaughnessy@mccarter.com

*Attorneys for Novartis Pharmaceuticals
Corporation*

OF COUNSEL:

Jane M. Love, Ph.D.
Robert Trenchard
Martin E. Gilmore
Sadaf R. Abdullah
WILMER CUTLER PICKERING
HALE AND DORR LLP
7 World Trade Center
250 Greenwich Street
New York, NY 10007
(212) 230-8800

Lisa J. Pirozzolo
WILMER CUTLER PICKERING
HALE AND DORR LLP
60 State Street
Boston, MA 02109
(617) 526-6000

Rachel L. Weiner
WILMER CUTLER PICKERING
HALE AND DORR LLP
1875 Pennsylvania Avenue, N.W.
Washington, DC 20006
(202) 663-6000

*Attorneys for Novartis Pharmaceuticals
Corporation*

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

NOVARTIS PHARMACEUTICALS
CORPORATION,

Plaintiff,

v.

ACTAVIS LLC; APOTEX, INC.;
APOTEX, CORP.; GLAND PHARMA
LTD.; DR. REDDY'S LABORATORIES,
INC.; DR. REDDY'S LABORATORIES
LTD.; EMCURE PHARMACEUTICALS
USA, INC.; EMCURE
PHARMACEUTICALS, LTD; HOSPIRA,
INC.; PHARMACEUTICS
INTERNATIONAL INC.; SAGENT
PHARMACEUTICALS, INC.; ACS
DOBFAR INFO S.A.; STRIDES, INC.;
AGILA SPECIALTIES PRIVATE LTD.;
SUN PHARMA GLOBAL FZE;
CARACO PHARMACEUTICAL
LABORATORIES, LTD; SUN
PHARMACEUTICAL INDUSTRIES
LTD.; WOCKHARDT USA LLC; and
WOCKHARDT LTD.

Defendants.

Civil Action No. 13-1028 (SDW) (MCA)

**NOVARTIS'S ANSWER TO THE COUNTERCLAIMS OF
PHARMACEUTICS INTERNATIONAL, INC.**

Novartis Pharmaceuticals Corporation ("Novartis"), by and through its undersigned attorneys, under Fed. R. Civ. P. 12, hereby submits this Answer to the counterclaims of Pharmaceutics International, Inc. ("Pii") to the Corrected Amended Complaint (D.I. 210, hereinafter "Counterclaims"). For the convenience of the Court, Novartis uses the section headings as posed by Pii in the Counterclaims, and does not purport to concur with the conclusions made therein. Accordingly, this Answer responds to those allegations as follows:

1. Defendant and Counterclaim-Plaintiff Pii is a corporation organized under Maryland law. Its principal place of business is in Hunt Valley, Maryland.

Admitted on information and belief.

2. Plaintiff Novartis is a corporation organized under Delaware law. Its principal place of business is in East Hanover, New Jersey. Novartis owns the ‘241, ‘987, and ‘189 patents.

Admitted.

3. This is a declaratory judgment action under the patent laws of the United States, 35 U.S.C. § 1, *et seq.* Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a).

Paragraph 3 states legal conclusions as to which no response is required. To the extent a response is required, Novartis admits that the Counterclaims purport to seek declaratory relief under the patent laws of the United States, 35 U.S.C § 1, *et seq.* Moreover, Novartis does not dispute that this Court has jurisdiction over the subject matter of this action.

4. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and 1400(b).

Paragraph 4 of the Counterclaims states a legal conclusion as to which no response is required. To the extent a response is required, for purposes of this action only, Novartis does not dispute that venue is proper in this judicial district.

5. This Court may declare the rights and legal relation for the parties pursuant to 28 U.S.C. §§ 2201 and 2202 and 35 U.S.C. § 271(e)(5).

Paragraph 5 of the Counterclaims states a legal conclusion as to which no response is required. To the extent a response is required, Novartis admits that the Court may declare certain rights and legal relations between Novartis and Pii. Novartis denies the remaining allegations of Paragraph 5.

6. Novartis has commenced the present action for patent infringement against Pii in this Court. An actual and justiciable controversy therefore exists between the parties.

Novartis admits that Novartis has commenced the present action. The remaining allegations of Paragraph 6 state legal conclusions as to which no response is required. To the extent a response is required, Novartis admits that an actual and justiciable controversy exists between Novartis and Pii. Novartis denies the remaining allegations of Paragraph 6.

COUNT I - DECLARATORY JUDGMENT OF NONINFRINGEMENT '241 PATENT

7. Pii incorporates by reference, as if fully set forth herein, the preceding paragraphs of its Answer and Counterclaim.

Novartis incorporates by reference each of its answers to Paragraphs 1-6 above as if fully set forth herein.

8. With respect to its generic Reclast product, Pii has not infringed and is not infringing any claim of the '241 patent, literally or under the doctrine of equivalents either directly or indirectly and has not induced infringement or contributed to infringement by others.

Denied.

9. The '241 patent is not listed in the Orange Book for the Zometa (4 mg/5 ml) product.

Admitted.

10. With respect to its generic Zometa (4 mg/5 ml) product, Pii has not infringed and is not infringing any claim of the '241 patent, literally or under the doctrine of equivalents either directly or indirectly and has not induced infringement or contributed to infringement by others.

Admitted.

COUNT II - DECLARATORY JUDGMENT OF NONINFRINGEMENT '987 PATENT

11. Pii incorporates by reference, as if fully set forth herein, the preceding paragraphs of its Answer and Counterclaim.

Novartis incorporates by reference each of its answers to Paragraphs 1-10 above as if fully set forth herein.

12. Pii has not infringed and is not infringing any claim of the '987 patent, literally or under the doctrine of equivalents either directly or indirectly and has not induced infringement or contributed to infringement by others.

Denied.

COUNT III - DECLARATORY JUDGMENT OF NONINFRINGEMENT '189 PATENT

13. Pii incorporates by reference, as if fully set forth herein, the preceding paragraphs of its Answer and Counterclaim.

Novartis incorporates by reference each of its answers to Paragraphs 1-12 above as if fully set forth herein.

14. Pii has not infringed and is not infringing any claim of the '189 patent, literally or under the doctrine of equivalents either directly or indirectly and has not induced infringement or contributed to infringement by others.

Denied.

COUNT IV - DECLARATORY JUDGMENT OF INVALIDITY '241 PATENT

15. Pii incorporates by reference, as if fully set forth herein, the preceding paragraphs of its Answer and Counterclaim.

Novartis incorporates by reference each of its answers to Paragraphs 1-14 above as if fully set forth herein.

16. Each and every claim of the '241 patent is invalid for failure to comply with the requirements of 35 U.S.C. §§ 102 and/or 103 for at least the reasons stated in Pii's Notice Letter dated August 16, 2012.

Denied.

17. Specifically, the claims of the '241 patent are invalid as anticipated and/or obvious over at least the following prior art references:

- a. Canadian Patent Application 2347330;**
- b. Patent Cooperation Treaty Publication No. WO 02/22136;**
- c. Patent Cooperation Treaty Publication No. WO 2001/089494;**
- d. Prior art Zometa® Product Label; and**
- e. Daikyo Rezin CZ®.**

Denied.

COUNT V - DECLARATORY JUDGMENT OF INVALIDITY '987 PATENT

18. Pii incorporates by reference, as if fully set forth herein, the preceding paragraphs of its Answer and Counterclaim.

Novartis incorporates by reference each of its answers to Paragraphs 1-17 above as if fully set forth herein.

19. Each and every claim of the '987 patent is invalid for failure to comply with the requirements of 35 U.S.C. §§ 101, 102, 103, and/or 112.

Denied.

20. Specifically, the claims of the '987 patent are invalid as anticipated and/or obvious over at least the following prior art references:

- a. Patent Cooperation Treaty Publication No. WO95/30421;**
- b. U.S. Patent No. 4,939,130;**
- c. Green et al., Preclinical Pharmacology of CGP 42'446, a New Potent, Heterocyclic Bisphosphonate Compound, J. Bone Min. Res., 9:5, 745-751 (1994); and**
- d. Heikkinen et al., Short-Term Intravenous Bisphosphonates in Prevention of Postmenopausal Bone Loss, J. Bone Min. Res., 12:1, 103-110 (1997).**

Denied.

21. The claims of the '987 patent are invalid for lack of utility, lack of written description and lack of enablement because the patent specification fails to describe that the inventors were in possession of the claimed invention and fails to enable a person of ordinary skill in the art to practice the full scope of the claimed invention.

Denied.

COUNT VI - DECLARATORY JUDGMENT OF INVALIDITY '189 PATENT

22. Pii incorporates by reference, as if fully set forth herein, the preceding paragraphs of its Answer and Counterclaim.

Novartis incorporates by reference each of its answers to Paragraphs 1-21 above as if fully set forth herein.

23. Each and every claim of the '189 patent is invalid for failure to comply with the requirements of 35 U.S.C. §§ 101, 102, 103, and/or 112 for at least the reasons stated in Pii's Notice Letter dated February 8, 2013.

Denied.

24. Specifically, the claims of the '189 patent are invalid as anticipated and/or obvious over at least the following prior art references:

- a. Berenson *et al.* *Proc. ASCO* 2000, 19:209a;**
- b. Body, *Cancer* 80(8):1699-1701 (1997);**
- c. Lipton *et al.*, *Eur. c. J. Cancer* 35, Suppl. 4: S360 (1999);**
- d. Major *et al.*, *Proc. ASCO* 2000, 19:605A; and**
- e. *Drugs of the Future*, 25(3):259-268 (2000).**

Denied.

25. The claims of the '189 patent are invalid for lack of definiteness because the claims are insolubly ambiguous.

Denied.

26. The claims of the '189 patent are invalid for lack of utility because they do no more than recite the natural phenomena of following conventional steps for administering zoledronic acid.

Denied.

ANSWER TO COUNTER-PLAINTIFFS' PRAYER FOR RELIEF

Novartis denies that Pii is entitled to the relief it seeks in Paragraphs (A) – (F), or any other relief with respect to allegations made in the Counterclaims.

DATED: May 20, 2013

s/ William J. O'Shaughnessy
William J. O'Shaughnessy
MCCARTER & ENGLISH LLP
Four Gateway Center
100 Mulberry Street
Newark, NJ 07102
(973) 639-2094
woshaughnessy@mccarter.com

*Attorneys for Novartis Pharmaceuticals
Corporation*

OF COUNSEL:

Jane M. Love, Ph.D.
Robert Trenchard
Martin E. Gilmore
Sadaf R. Abdullah
WILMER CUTLER PICKERING
HALE AND DORR LLP
7 World Trade Center
250 Greenwich Street
New York, NY 10007
(212) 230-8800

Lisa J. Pirozzolo
WILMER CUTLER PICKERING
HALE AND DORR LLP
60 State Street
Boston, MA 02109
(617) 526-6000

Rachel L. Weiner
WILMER CUTLER PICKERING
HALE AND DORR LLP
1875 Pennsylvania Avenue, N.W.
Washington, DC 20006
(202) 663-6000

*Attorneys for Novartis Pharmaceuticals
Corporation*

CERTIFICATE OF SERVICE

The undersigned hereby certifies that true copies of the foregoing **NOVARTIS'S ANSWER TO THE COUNTERCLAIMS OF PHARMACEUTICS INTERNATIONAL, INC.** was caused to be served May 20, 2013 via email and/or ECF system upon all counsel of record.

By: s/ William J. O'Shaughnessy
William J. O'Shaughnessy